Complete Summary

GUIDELINE TITLE

Guidance on the use of ultrasound locating devices for placing central venous catheters.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of ultrasound locating devices for placing central venous catheters. London (UK): National Institute for Clinical Excellence (NICE); 2002 Sep. 21 p. (Technology appraisal guidance; no. 49).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease/condition that requires a central venous catheter (CVC) insertion for treatment/monitoring (either electively or in an emergency situation)

GUIDELINE CATEGORY

Technology Assessment

CLINICAL SPECIALTY

Cardiology
Critical Care

Emergency Medicine
Infectious Diseases
Internal Medicine
Nursing
Oncology
Preventive Medicine
Pulmonary Medicine
Radiology
Surgery
Thoracic Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To investigate the clinical effectiveness and cost-effectiveness of using ultrasound locating devices (ULDs) for the placement of central venous catheters

TARGET POPULATION

Adults and children undergoing elective or emergency procedures that require central venous catheter (CVC) insertion

INTERVENTIONS AND PRACTICES CONSIDERED

1. Two-dimensional (2-D) imaging ultrasound guidance for insertion of central venous catheters (CVCs)
2. Appropriate training all those involved in placing CVCs using two dimensional (2-D) imaging ultrasound guidance

Note: Audio-guided Doppler ultrasound guidance was considered but is not recommended for CVC insertion.

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Number of failed catheter placements
    - Number of catheter placement complications
    - Risk of Failure on the First catheter placement attempt
    - Number of attempts to successful catheteirisation
    - Number of seconds to successful catheterization
    - Rate of success after failure by the alternate method
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield. (See the "Availability of Companion Documents" field.)

Effectiveness

Search Strategy

The search aimed to identify references related to ultrasound locating devices and central venous lines. The searches were conducted in September and October 2001.

Sources Searched

Fifteen electronic bibliographic databases were searched, covering biomedical, science, social science, health economic, and grey literature (including current research). A list of databases is provided in Appendix 1 of the Assessment Report (see "Availability of Companion Documents" field).

In addition, the reference lists of relevant articles were checked and various health services research related resources were consulted via the Internet. These included health economics and health technology assessment (HTA) organisations, guideline producing agencies, generic research and trials registers, and specialist sites. A list of these additional sources is given in Appendix 2 of the Assessment Report (see "Availability of Companion Documents" field).

The sponsor submissions were hand searched for any new potential randomised controlled trial citations.

Search Terms

A combination of free-text and thesaurus terms were used. Central venous line search terms (e.g., catheterisation, central venous/, central venous line, PICC, venous cannulation, central venous catheter, pulmonary artery flotation, central line insertion, Hickman line, etc.) were combined with "ultrasound" terms (e.g.,

ultrasonics, ultrasonography, imaged guidance, ultrasound, Doppler, etc.) Copies of the search strategies used in the major databases are included in Appendix 3 of the Assessment Report (see "Availability of Companion Documents" field).

Search Restrictions

Where possible (e.g. in the smaller databases), searches were not restricted by publication type or study design. However, methodological filters aimed at identifying guidelines, systematic reviews, clinical trials, economic evaluations, and quality of life studies, were used in Medline (refer to Appendix 4 of the Assessment Report [see "Availability of Companion Documents" field] for details of the filters used). Date and language restrictions were not used.

Inclusion and Exclusion Criteria

Only studies of the clinical effectiveness of using ultrasound or Doppler ultrasound for locating devices for the placement of central venous lines were included. In terms of patient populations, only studies on groups requiring the placement of central venous lines were included. In terms of comparators, only studies assessing 2-D ultrasound/Doppler ultrasound against the landmark method, or the surgical cutdown procedure were included. Only studies with one or more of the following outcomes were included: number of failed catheter placements, number of catheter placement complications, risk of failure on the first catheter placement attempt, number of attempts to successful catheterisation, number of seconds to successful catheterisation, rate of success after failure by the alternate method (where a crossover design was incorporated).

The abstracts of potentially relevant citations were reviewed. After examining the full manuscripts of all potentially relevant abstracts, those deemed to be potential randomised controlled trials relating directly to the scope question were obtained, i.e., the effectiveness of ultrasonic locating device (ULD) against the landmark method or surgical cutdown procedure with respect to central venous access.

All non-English language papers were excluded, as were trials with a quasi-random design. Trials that dealt with the use of ultrasound for vessel localisation, but not for insertion, were dealt with separately from those that dealt with both.

NUMBER OF SOURCE DOCUMENTS

There were 20 prospective, randomised trials (including two abstracts), as well as one meta-analysis, assessing 2-D ultrasound-guided vessel localisation followed by 2-D ultrasound-guided venepuncture versus a control, three of which incorporated a cross-over element (see Appendix 5, Table 8 of the Assessment Report [see "Availability of Companion Documents" field]). There were also two prospective, randomized trials concerned with Doppler ultrasound-guided vessel localization followed by blind venepuncture.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield. (See the "Availability of Companion Documents" field.)

Data Extraction Strategy

Data extraction was undertaken by one researcher and checked by another. Disagreement was resolved by consensus. Data on the number of catheters and/or the number of patients were abstracted the way they were reported, as were data about mechanical complications. The numbers of patients with complications were pooled for purposes of meta-analysis; where known, the individual complications were reported in Table 13, Appendix 5 of the Assessment Report (see "Availability of Companion Documents" field). Catheters were the unit of analysis when data were pooled, which is to say that the number of catheter placements, rather than the number of patients were recorded.

Quality Assessment Strategy

Randomised controlled trials were not rated according to the validated quality scale devised by Alejandro Jadad and others. This is because the Jadad system relies heavily on blinding without allowing for the fact that blinding is not possible in trials of certain interventions (ultrasonic locating devices [ULDs] being a case in point). Instead, a component approach was adopted to assess trial quality. This took into account six individual quality domains and their associated biases.

First, the number of patient characteristics reported out of five key variables was recorded: the greater number, the greater the external validity of the study. Following the approach taken by Randolph et al., the selected variables were age, sex, diagnoses, coagulopathy, and body surface area or height weight ratio. The last two are commonly associated with risk assessment in the insertion of central venous catheters. Second, the standardisation of the insertion method was recorded, a factor affecting the internal statistical validity of the trial. Third, the method of randomisation was recorded, where reported, to assess the potential for bias. Fourth and fifth, the number of post-randomisation exclusions was recorded, as well as whether or not intention-to-treat analysis was performed.

These last two factors were included to reflect the potential presence of attrition bias.

Data Analysis

Data analysis was performed using the Cochrane Collaboration's Review Manager 4.1 software package. Data to estimate the relative risk and associated 95% confidence limits across studies using the random effects model were combined. Statistical heterogeneity (major differences between studies in the estimates of apparent effects of the interventions) was tested for to assess whether the observed variance in effect size between studies is greater than that expected to occur by chance. Using the null hypothesis that the relative risks were the same across studies, the p-value for the heterogeneity test indicates the statistical significance of the differences in study results. The significance of this p-statistic in the test for heterogeneity is that the pooling of studies that are shown to be heterogeneous can lead to the reporting of insignificant p-values for the outcome variable of interest, when this p-value may actually be significant for homogeneous subsets of the pooled studies. A significant outcome variable p-value, combined with a significant heterogeneity test p-value result, implies that the outcome variable is statistically significant despite the presence of heterogeneity.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and

commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

No relevant economic evaluations were identified in the literature. Furthermore, none of the submissions made to the Institute included economic evaluations.

The Assessment Group developed an economic analysis, based on the evidence from the systematic review of randomised controlled trials (RCTs), to evaluate the cost effectiveness of 2-D ultrasound guidance compared with the landmark method. This model is a simple decision analytic model, and is based on a theoretical cohort of 1000 adult patients who required inferior jugular vein (IJV) cannulation before surgery and who had a low to moderate risk of complications.

This model adopted a set of conservative assumptions. It was assumed that: the operators were experienced in using the landmark method; the time to achieve successful puncture was the same for both methods; complications were limited to arterial puncture; there was a 10-minute delay between the prior failure and the new attempt at another insertion site; there was a 100% success rate at the second insertion site; and each machine was used for 15 procedures per week.

The results of the Assessment Group's model suggested that the ultrasound guidance not only avoided 90 arterial punctures for every 1000 patients treated, but also reduced costs by an average of almost 2 pounds sterling per patient. In other words the 2-D ultrasound guidance method was found to be both more effective and less costly than the landmark method.

A threshold sensitivity analysis was undertaken to examine by how much key variables in the model needed to change to make the ultrasound guidance method cost-neutral instead of cost-saving. The modelled result was most sensitive to the utilisation of the ultrasound equipment. The cost-saving result was eradicated if the number of ultrasound procedures assumed per machine per week was less than around 11, or if the number of ultrasound procedures carried out by an individual trained practitioner was less than around 3 per month on average.

Given that the model used relatively conservative estimates, the Assessment Group concluded that the results were probably generalisable to all anatomical catheter insertion sites, to infants, and to other sites within the hospital including the clinical wards.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Two-dimensional (2-D) imaging ultrasound guidance is recommended as the preferred method for insertion of central venous catheters (CVCs) into the internal jugular vein (IJV) in adults and children in elective situations.
- The use of two-dimensional (2-D) imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary either electively or in an emergency situation.
- It is recommended that all those involved in placing CVCs using two dimensional (2-D) imaging ultrasound guidance should undertake appropriate training to achieve competence.

- Audio-guided Doppler ultrasound guidance is not recommended for CVC insertion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate placement of central venous catheters to minimise the risk of adverse events such as failed catheter placements or catheter placement complications

POTENTIAL HARMS

Complications associated with central venous catheter insertion including arterial puncture, wrong position of catheter, hematoma

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- National Health Service (NHS) Trusts in which central venous catheters (CVCs) are used, all those who routinely insert CVCs, and those responsible for clinical training programmes should review policies and practices regarding the insertion of CVCs to take account of the guidance (see the "Major Recommendations" field). The recommendations in this guidance will represent a significant service development for most NHS organisations. The Appraisal Committee has advised the Institute that the nature of the resource consequences of the guidance and the time it will take to put them in place

should be brought to the attention of the Department of Health and the Welsh Assembly Government.
- Local guidelines or care pathways which relate to the use of CVCs should incorporate the guidance (see the "Major Recommendations" field).
- To enable healthcare practitioners to audit their own compliance with this guidance, it is recommended that a system is available to identify patients who have a CVC inserted in either an elective or an emergency situation.
- To measure compliance locally with the guidance (see the "Major Recommendations" field), the following criteria should be used. Further details on suggestions for audit are presented in Appendix D of the original guideline document.
    - When a CVC is being inserted into the inferior jugular vein (IJV) of an adult or a child in an elective situation, 2-dimensional (2-D) imaging ultrasound guidance is used.
    - All healthcare practitioners involved in the placement of CVCs using 2-D imaging ultrasound guidance undertake appropriate training to achieve competence in this technique.
    - Audio-guided Doppler ultrasound guidance is not used for CVC insertion.
- All NHS Trusts in which CVCs are used should identify the number of 2-D imaging ultrasound units required and the appropriate location for each unit, should plan to train a sufficient number of healthcare practitioners from a range of disciplines in the proper use of the units, and should identify other financial and service implications of implementing the guidance (see the "Major Recommendations" field).
- Healthcare practitioners should consider the most appropriate method of CVC insertion that is in the best interest of the patient in his or her specific clinical situation, particularly in terms of minimising the risk of adverse events such as failed catheter placements or catheter placement complications. Trusts should recognise that the decision to use 2-D imaging ultrasound guidance or the landmark method will be informed by:
    - The competence and previous experience of the operator(s)
    - The anatomical site of CVC insertion and other anticipated technical difficulties
    - The urgency of clinical need

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of ultrasound locating devices for placing central venous catheters. London (UK): National Institute for Clinical Excellence (NICE); 2002 Sep. 21 p. (Technology appraisal guidance; no. 49).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Sep

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Jane Adam, Radiologist, St George's Hospital, London; Professor R L Akehurst, Dean, School of Health Related Research, Sheffield University; Dr Sunil Angris, General Practitioner, Waterhouses Medical Practice; Professor David Barnett (Chairman) Professor of Clinical Pharmacology, University of Leicester; Dr Sheila Bird, MRC Biostatistics Unit, Cambridge; Professor Carol Black, Consultant Physician, Royal Free Hospital & UCL, London; Professor John Brazier, Health Economist, University of Sheffield; Professor Martin Buxton, Director of Health Economics Research Group, Brunel University; Professor Mike Campbell, Statistician, Institute of General Practice & Primary Care, Sheffield; Dr Karl Claxton, Health Economist, University of York; Professor Sarah Cowley, Professor of Community Practice Development, Kings College, London; Professor Jack Dowie, Health Economist, London School of Hygiene & Tropical Medicine, London; Mr Chris Evennett, Chief Executive, Mid-Hampshire Primary Care Trust;

Dr Paul Ewings, Statistician, Taunton & Somerset NHS Trust; Professor Terry Feest, Clinical Director and Consultant Nephrologist, Richard Bright Renal Unit, and Chairman of the UK Renal Registry; Professor Gary A Ford, Professor of Pharmacology of Old Age/Consultant Physician, Wolfson Unit of Clinical Pharmacology, University of Newcastle; Mrs Sue Gallagher, Chief Executive, Merton, Sutton and Wandsworth Health Authority; Dr Trevor Gibbs, Head, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline; Sally Gooch, Director of Nursing, Mid-Essex Hospital Services Trust; Mr John Goulston, Director of Finance, The Royal Free Hampstead NHS Trust; Professor Trisha Greenhalgh, Professor of Primary Health Care, University College London; Miss Linda Hands, Consultant Vascular Surgeon, John Radcliffe Hospital, Oxford; Professor Philip Home, Professor of Diabetes Medicine, University of Newcastle; Dr Terry John, General Practitioner, The Firs, London; Dr Diane Ketley, Research into Practice Programme Leader, NHS Modernisation Agency; Dr Mayur Lakhani General Practitioner, Highgate Surgery, Leicester, and Lecturer, University of Leicester; Ruth Lesirge, Lay Representative; Director, Mental Health Foundation; Dr George Levvy, Lay Representative; Chief Executive, Motor Neurone Disease Association; Dr Gill Morgan, CEO, North & East Devon Health Authority; Professor Miranda Mugford, Health Economist, University of East Anglia; Mr M Mughal, Consultant Surgeon, Lancashire Teaching Hospitals NHS Trust; Mr James Partridge, Lay Representative; Chief Executive, Changing Faces; Siân Richards, General Manager, Cardiff Local Health Group; Professor Philip Routledge, Professor of Clinical Pharmacology, University of Wales; Dr Rhiannon Rowsell, Pharmaceutical Physician, AstraZeneca UK Ltd; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Professor Andrew Stevens (Vice-Chairman) Professor of Public Health, University of Birmingham; Professor Ray Tallis, Consultant Physician, Hope Hospital, Salford; Dr Cathryn Thomas, General Practitioner, and Senior Lecturer, Department of Primary Care and General Practice, University of Birmingham; Professor Mary Watkins, Head of Institute of Health Studies, University of Plymouth; Dr Norman Waugh, Public Health Consultant, University of Southampton

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance on the use of ultrasound locating devices for placing central venous catheters. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Aug. 1 p. (Technology appraisal 49). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- The effectiveness and cost-effectiveness of ultrasound locating devices for central venous access. Assessment report. NHS R&D HTA Programme; 2002 Jan 24. 98 p. Available in Portable Document Format (PDF) from the NICE Web site.
- A survey measuring the impact of NICE guidance 49: The use of ultrasound locating devices for placing central venous catheters. Abacus International Survey; 2004 Jul. 18 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0147. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix D of the original guideline document.

PATIENT RESOURCES

The following is available:

- Guidance on the use of ultrasound locating devices for placing central venous catheters. Information for patients. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Sep. 8 p. (Technology appraisal 49).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N0148. 11 Strand, London, WC2N 5HR.

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NGC STATUS

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